



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

July 2, 2002

**MEMORANDUM:**

**Subject:** Efficacy Review for EPA Reg. No.: 5813-TL, "Clorox®Trapeze"  
DP Barcodes: D282023  
Case No.: 071584

**From:** Emily Mitchell, M.S., Team Leader *Emily Mitchell 7/9/02*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

**Through:** Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

**To:** Adam Heyward, PM 34/Renae Whitaker  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**Formulation From Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Poly(hexamethylenebiguanide) hydrochloride.....	0.10%
<u>Inert Ingredients(s)</u> .....	99.90%
	100.00%

## **SUMMARY OF INFORMATION REVIEWED AND FINDINGS/CONCLUSIONS:**

DynCorp I&ET efficacy review has undergone secondary review by AD/PSB/EET. The contractor's review reflect EPA's Pesticide Assessment Guideline requirements and regulations and the findings/conclusions are scientifically sound. However, do not include comments that are not appropriate. (See comments listed below)

**REGULATORY REVIEWER:** Please delete comments in all appropriate places that state "EPA would need to determine whether the performance standard used (and achieved) by the laboratory, at variance with ASTM E1153, is acceptable prior to accepting the label claims". Please note that ASTM E1153 is an acceptable method by the Agency. If the samples are 60 days old (need verification from registrant or testing laboratory) then the data for *Enterobacter aerogenes* and *Staphylococcus aureus* are acceptable for Formula 2001.0086. Additional organisms are also acceptable if the above criteria is met. The Formula 2001.0093 can only be registered after the efficacy data requirements for Formula 2001.0086 have been satisfied. The regulatory reviewer should also make sure the identity of the product is actually Clorox Trapeze. See comments from contractor's review under General Recommendations, #2. Under label comments make sure to inform the registrant that "new" can only appear on label for 6 months. Clarification for types of germs and bacteria must appear on the label. Also make sure they delete comparative statements such as "America's home floor sanitizer and/or cleaner", "Effective sanitizing has never been faster or easier", and "Fast acting sanitizer."

**NOTE TO PM:** A copy of DynCorp I&ET Efficacy Evaluation Report dated June 24, 2002 is appended to our memorandum. Our secondary review projects Findings/Conclusions to assist regulatory in communicating the Agency's decisions to the applicant.

## **MEMORANDUM**

DATE: June 24, 2002

SUBJECT: Efficacy Review for Clorox Trapeze, EPA Reg. 005813-TL;  
DP Barcode: D282023

FROM: DynCorp I&ET

THRU: Ian Blackwell  
Antimicrobials Division

TO: Emily Mitchell  
Antimicrobials Division

APPLICANT: The Clorox Company  
Pleasanton, California

### **I BACKGROUND**

The product 005813-TL, Clorox Trapeze, is being reviewed as a ready-to-use sanitizer for use on non-food contact floor surfaces in homes, bathrooms, and kitchens. The applicant requested to register a new product. All studies were conducted at The Clorox Technical Center, 7200 Johnson Drive, Pleasanton, California 94588 and AppTec Laboratory Services, 2540 Executive Drive, St. Paul, Minnesota 55120.

This data package contained nine studies (MRID Nos. 456290-07 through 456290-14 and 456290-16), Statements of No Data Confidentiality Claims for all nine studies, a Summary of Trapeze GLP Testing, and the proposed label. The data package also included a study entitled "Efficacy of Clorox Trapeze in ReadyMop System on Floor Bacteria", assigned MRID 456290-15. As directed by EPA, DynCorp did not summarize or evaluate this study.

Note: The EPA Data Package Record Bean Sheet and proposed label refer to the product as Clorox Trapeze; however, MRID Nos. 456290-07 through 45629-14 refer to the product as Clorox DOA.

Note: The applicant submitted data for two formulations of the product (i.e., F2001.0086 and F2001.0093). Information in the data package asserted that the two formulations differ only by their fragrance. Information in the data package made available to DynCorp does not include Confidential Statements of Formula; therefore, DynCorp was not able to verify whether the two formulations are effectively identical.

## II USE DIRECTIONS

The product is designed to be used with the ReadyMop Mopping System for sanitizing and deodorizing hard, non-porous surfaces in homes. The proposed label directions read as follows: "To clean: Pull trigger to dispense liquid. While mopping, spread liquid uniformly over floor with pad. To sanitize: Pull trigger to dispense liquid. While mopping, spread liquid uniformly over floor with pad. Treated surface must remain visibly wet for 30 seconds before air drying. [For wood floors, use the specially designed Clorox ReadyMop Absorbent cleaning pads to dry floor thoroughly after 30 seconds.] . . . For best results, vacuum or sweep up large crumbs and dust before using the Clorox ReadyMop Mopping System."

The proposed label noted that the product is not recommended for use on visibly worn, unsealed, unfinished, waxed or oiled wood floors and is specially designed for no mixing and no rinsing.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

### Sanitizers for Non-Food Contact Surfaces

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-10 may be used. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different batches, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product already registered as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different batches, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Furthermore, according to information provided in Section 12.3.2 of ASTM Method E1153-94, which is a test method for the efficacy of sanitizers for non-food contact surfaces, "an average of at least  $7.5 \times 10^5$  organisms must have survived on the inoculated control squares for the test to be valid."

## Minor Formulation Change in a Registered Product

Minor formulation changes include, for example, a change of an inert ingredient. An applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and submit only minimal confirmatory efficacy data on the finished product to demonstrate the applicant's ability to produce an effective formulation. Label claims and directions for use must be unchanged from those accepted for the registered formulation, and specific references to the supporting data developed for the original formulation must be cited by the applicant. These Agency standards are located in DIS/TSS-5.

### IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

#### **1. MRID 456290-07 "Clorox Formula F2001.0086-Non-Food Contact Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 15, 2002.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038) and *Staphylococcus aureus* (ATCC 6538). The study protocol followed Clorox SOP No. 001-055-5 (not provided), a modification of ASTM E1153. Three batches (Lot Nos. 7890-85A (labeled "Aged"), 7890-129A, and 7890-129B) of the product were tested on glass, polyvinyl chloride, and glazed ceramic carriers. [Information to verify whether one of the lots tested was at least 60 days old at the time of the experiment was not provided in the MRID. Although information provided in MRID 456290-14 indicated that samples of two of the same lots were received by the laboratory on July 25, 2001, it is still unclear whether at least one lot tested was at least 60 days old at the time of the experiment. The experiment start date for the study was September 11, 2001.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch, test organism, and carrier type combination, five carriers [25 x 25 mm] were contaminated with 20 µL of a 48-54 hour old culture and dried at 35±2°C in a plastic desiccator with a glycerin solution for approximately 35 minutes. Each carrier was sprayed 2-3 times from a distance of 6-8 inches and allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth and shaken vigorously for neutralization. Within 30 minutes of neutralization, duplicate volumes of 1 mL and 0.1 mL aliquots from the broth with carriers were plated using Lethen Agar. All plates were incubated at 30±2°C for *Enterobacter aerogenes* and 35±2°C for *Staphylococcus aureus* for 48-54 hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred to as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

**2. MRID 456290-08 "Clorox Formula F2001.0093-Non-Food Contact Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 15, 2002.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038) and *Staphylococcus aureus* (ATCC 6538). The study protocol followed Clorox SOP No. 001-055-5 (not provided), a modification of ASTM E1153. Two batches (Lot Nos. 7890-130A and 7890-130B) of the product were tested on glass, polyvinyl chloride, and glazed ceramic carriers. [Information to verify whether one of the lots tested was at least 60 days old at the time of the experiment was not provided in the MRID.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch, test organism, and carrier type combination, five carriers were contaminated with 20  $\mu$ L of a 48-54 hour old culture and dried at  $35\pm 2^{\circ}\text{C}$  in a plastic desiccator with glycerin solution for approximately 35 minutes. Each carrier was sprayed 2-3 times from a distance of 6-8 inches and allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth and shaken vigorously for neutralization. Within 30 minutes of neutralization, duplicate volumes of 1 mL and 0.1 mL aliquots from the broth with carriers were plated using Letheen Agar. All plates were incubated at  $30\pm 2^{\circ}\text{C}$  for *Enterobacter aerogenes* and  $35\pm 2^{\circ}\text{C}$  for *Staphylococcus aureus* for 48-54 hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred to as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

**3. MRID 456290-09 "Clorox Formula F2001.0086-Non-Food Contact Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 15, 2002.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038) and *Staphylococcus aureus* (ATCC 6538). The study protocol followed Clorox SOP No. 001-055-5 (not provided), a modification of ASTM E1153. Three batches (Lot Nos. 7890-85A (labeled "Aged"), 7890-129A, and 7890-129B) of the product were tested on unglazed ceramic carriers. [Information to verify whether one of the lots tested was at least 60 days old at the time of the experiment was not provided in the MRID. Although information provided in MRID 456290-14 indicated that samples of two of the same lots were received by the laboratory on July 25, 2001, it is still unclear whether at least one lot tested was at least 60 days old at the time of the experiment. The experiment start date for the study was September 14, 2001.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch and test organism, five carriers [25 x 25 mm] were contaminated with 30  $\mu$ L of a 48-54 hour old culture and dried at  $35\pm 2^{\circ}\text{C}$  in a plastic desiccator with a glycerin solution for

approximately 35 minutes. Each carrier was sprayed 2-3 times from a distance of 6-8 inches and allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth and sonicated and shaken vigorously for neutralization. Within 30 minutes of neutralization, duplicate volumes of 1 mL and 0.1 mL aliquots from the broth with carriers were plated using Lethen Agar. All plates were incubated at  $30\pm 2^{\circ}\text{C}$  for *Enterobacter aerogenes* and  $35\pm 2^{\circ}\text{C}$  for *Staphylococcus aureus* for 48-54 hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred to as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

Note: Protocol amendments/deviations were reviewed and found to be acceptable.

**4. MRID 456290-10 "Clorox Formula F2001.0093-Non-Food Contact Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 15, 2002.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038) and *Staphylococcus aureus* (ATCC 6538). The study protocol followed Clorox SOP No. 001-055-5 (not provided), a modification of ASTM E1153. Two batches (Lot Nos. 7890-130A and 7890-130B) of the product were tested on unglazed ceramic carriers. [Information to verify whether one of the lots tested was at least 60 days old at the time of the experiment was not provided in the MRID.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch and test organism, five carriers [25 x 25 mm] were contaminated with 30  $\mu\text{L}$  of a 48-54 hour old culture and dried at  $35\pm 2^{\circ}\text{C}$  in a plastic desiccator with glycerin solution for approximately 35 minutes. Each carrier was sprayed 2-3 times from a distance of 6-8 inches and allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth and sonicated and shaken vigorously for neutralization. Within 30 minutes of neutralization, duplicate volumes of 1 mL and 0.1 mL aliquots from the broth with carriers were plated using Lethen Agar. All plates were incubated at  $30\pm 2^{\circ}\text{C}$  for *Enterobacter aerogenes* and  $35\pm 2^{\circ}\text{C}$  for *Staphylococcus aureus* for 48-54 hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred to as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

Note: Protocol amendments/deviations were reviewed and found to be acceptable.

**5. MRID 456290-11 "Clorox Formula F2001.0086-ReadyMop Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 22, 2002.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038) and *Staphylococcus aureus* (ATCC 6538). The study protocol followed Clorox SOP No. 001-158 (not provided), a modification of ASTM E1153. Three batches (Lot Nos. 7890-85A (labeled "Aged"), 7890-129A and 7890-129B) of the product were tested on glass, polyvinyl chloride, and glazed ceramic carriers. [Information to verify whether one of the lots tested was at least 60 days old at the time of the experiment was not provided in the MRID. However, information provided in MRID 456290-14 indicated that samples of two of the same lots were received by the laboratory on July 25, 2001. Based on this information, it is likely that at least two lots tested (Lot Nos. 7890-129A and 7890-129B) were at least 60 days old at the time of the experiment. The experiment start dates for the study were December 17, 2001 and an unspecified date in January 2002.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch, test organism and carrier type combination, five carriers were contaminated with 20  $\mu$ L of a 48-54 hour old culture and dried at  $35\pm 2^{\circ}\text{C}$  for approximately 35 minutes in a plastic desiccator with glycerin solution. [The *Enterobacter aerogenes* culture used for inoculating the glass carriers was a 46 hour culture.] [Glass carriers inoculated with *Enterobacter aerogenes* were dried for 30 minutes. Glazed ceramic carriers inoculated with *Enterobacter aerogenes* were dried for 32 minutes.] Using an assembled floor cleaning tool and wetted applicator pad, the test carriers were exposed by three 1-second trigger doses of the test product. This dose was applied using four complete cycles with the tool applicator, using slight pressure to ensure proper contact. After the last cycle, carriers were allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth shaken for five minutes for neutralization and serial diluted. Duplicate aliquots from the broth with carriers were plated using Lethen Agar. All plates were incubated at  $30\pm 2^{\circ}\text{C}$  for *Enterobacter aerogenes* and  $35\pm 2^{\circ}\text{C}$  for *Staphylococcus aureus* for  $48\pm 4$  hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred to as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

Note: The applicant provided invalid data from a failed study. The laboratory claimed that all glass carrier studies were performed under compromised conditions.

Note: Protocol amendments/deviations were reviewed and found to be acceptable.

**6. MRID 456290-12 "Clorox Formula F2001.0093-ReadyMop Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 12, 2002.**

This study was conducted against *Enterobacter aerogenes* (ATCC 15038) and *Staphylococcus aureus* (ATCC 6538). The study protocol followed Clorox SOP No. 001-158 (not provided), a modification of ASTM E1153. Two batches (Lot Nos. 7890-130A and 7890-130B) of the product were tested on polyvinyl chloride carriers. [Information to verify whether one of the lots tested was at least 60 days old at the time of the experiment was not provided in the MRID.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch and test organism, five carriers were contaminated with 20 µL of a 48-54 hour old culture and dried at 35±2°C for approximately 35 minutes in a plastic desiccator with glycerin solution. Using an assembled floor cleaning tool and wetted applicator pad, the test carriers were exposed by two to three 1-second trigger doses of the test product. The dose was then applied using four complete cycles with the tool applicator, using slight pressure to ensure contact. After the last cycle, the carriers were allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth shaken for neutralization and serially diluted. Duplicate aliquots from the broth with carriers were plated using Lethen Agar. All plates were incubated at 30±2°C for *Enterobacter aerogenes* and 35±2°C for *Staphylococcus aureus* for 48±4 hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

**7. MRID 456290-13 "Clorox Formula F2001.0086-ReadyMop Sanitizer Test" for Clorox Trapeze, by Denis Haire. Study performed at The Clorox Technical Center. Study completion date – February 12, 2002.**

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). The study protocol followed Clorox SOP No. 001-158 (not provided), a modification of ASTM E1153. Two batches (Lot Nos. 7890-129A and 7890-129B) of the product were tested on polyvinyl chloride carriers. Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch, five carriers were contaminated with 20 µL of a 48-54 hour old culture and dried at 35±2°C in a plastic desiccator with glycerin solution for approximately 25 minutes. Using an assembled floor cleaning tool and wetted applicator pad, the test carriers were exposed by three 1-second trigger doses of the test product. The dose was then applied using four complete cycles with the tool applicator, using slight pressure to ensure

contact. After the last cycle, the carriers were allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth, shaken for five minutes for neutralization, and serially diluted. Duplicate aliquots from the broth with carriers were plated using Lethen Agar. All plates were incubated at  $35 \pm 2^\circ\text{C}$  for  $48 \pm 4$  hours. Controls included: carrier controls, neutralization verification, and sterility.

Note: The test product was referred as Clorox DOA.

Note: The laboratory indicated an acceptance criterion of  $7.5 \times 10^4$  CFU/carrier for the geometric mean of the carrier control count, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

Note: The applicant provided the invalid data from a failed trial. In that trial, the geometric mean of the carrier control count for *Salmonella choleraesuis* ( $2.75 \times 10^4$  CFU/carrier) was below the laboratory's acceptance criterion of  $7.5 \times 10^4$  CFU/carrier.

Note: Protocol amendments/deviations were reviewed and found to be acceptable.

**8. MRID 406628-14 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application), Test Organisms: *Salmonella choleraesuis* (ATCC 10708), *Escherichia coli* O157:H7 (ATCC 43888)" for Clorox Trapeze, Formula F2001.0086, by Andrea J. Mesaros. Study performed at AppTec Laboratory Services. Study completion date – February 28, 2002.**

This study was conducted against *Salmonella choleraesuis* (ATCC 10708) and *Escherichia coli* O157:H7 (ATCC 43888). The study protocol followed ASTM E1153, modified for spray products. Two batches (Lot Nos. 7890-129A and 7890-129B) of the product were tested on glass, glazed ceramic, unglazed ceramic, and polyvinyl chloride carriers. [Both lots tested were at least 60 days old at the time of the experiment.]. Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch, five carriers were contaminated with 0.03 mL of a  $48 \pm 4$  hour old culture and dried at  $36^\circ\text{C}$  for approximately 20 minutes. For each product batch, five carriers were sprayed at a distance of 6-8 inches with 2-3 pumps at staggered intervals and allowed to sit for 30 seconds at room temperature ( $20^\circ\text{C}$ - $22^\circ\text{C}$ ). Each carrier was then transferred into 20 mL of D/E Broth. Each container was then rotated vigorously for approximately 50 rotations for neutralization. The unglazed tiles were sonicated in a water bath for 3 minutes after neutralization and prior to rotation. Within 30 minutes of neutralization, duplicate volumes of 1 mL and 0.1 mL aliquots from the broth with carriers were plated using blood agar. All plates were incubated at  $36^\circ\text{C}$  for  $48 \pm 4$  hours. Controls included: carrier controls, neutralization confirmation, purity, and sterility.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

Note: The laboratory indicated an acceptance criterion of  $2.0 \times 10^4$  CFU/carrier for the carrier controls, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The applicant provided the invalid data from failed trials, which were set up on September 25, 2001 and again on October 24, 2001. In those trials, the carrier control count for *Salmonella choleraesuis* ( $<2.0 \times 10^3$  CFU/carrier on September 25, 2001 and  $1.7 \times 10^3$  CFU/carrier on October 24, 2001) and for *Escherichia coli* O157:H7 ( $<2.0 \times 10^3$  CFU/carrier on September 25, 2001) were below the laboratory's acceptance criterion of  $2.0 \times 10^4$  CFU/carrier.

Note: Protocol amendments/deviations were reviewed and found to be acceptable.

**9. MRID 406628-16 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" for Clorox Trapeze, Formula F2001.0093, by Andrea J. Mesaros. Study performed at AppTec Laboratory Services. Study completion date – February 28, 2002.**

This study was conducted against *Salmonella choleraesuis* (ATCC 10708) and *Escherichia coli* O157:H7 (ATCC 43888). The study protocol followed ASTM E1153, modified for spray products. Two batches (Lot Nos. 7890-130A and 7890-130B) of the product were tested on glass, glazed ceramic, unglazed ceramic and polyvinyl chloride carriers. [Both lots tested were at least 60 days old at the time of the experiment.] Fetal bovine serum was added to the test organism inoculum to produce a 5% organic soil load. For each product batch, five carriers were contaminated with 0.03 mL of a  $48 \pm 4$  hour old culture and dried at  $36^\circ\text{C}$  for approximately 20 minutes. For each product batch, five carriers were sprayed at a distance of 6-8 inches with 2-3 pumps at staggered intervals and allowed to sit for 30 seconds at room temperature. Each carrier was then transferred into 20 mL of D/E Broth. Each container was then rotated vigorously for approximately 50 rotations for neutralization. The unglazed tiles were sonicated in a water bath for 3 minutes after neutralization and prior to rotation. Within 30 minutes of neutralization, duplicate volumes of 1 mL and 0.1 mL aliquots from the broth with carriers were plated using blood agar. All plates were incubated at  $36^\circ\text{C}$  for  $48 \pm 4$  hours. Controls included: carrier controls, neutralization confirmation, purity, and sterility.

Note: The product lots were evaluated before and after the study for the active levels of the active ingredient. Active levels were found to be within the expected range.

Note: The laboratory indicated an acceptance criterion of  $2.0 \times 10^4$  CFU/carrier for the carrier controls, which differs from the  $7.5 \times 10^5$  CFU/carrier criterion indicated in ASTM Method E1153.

Note: The applicant provided the invalid data from failed trials, which were set up on September 26, 2001 and again on October 24, 2001. In those trials, the carrier control count for *Salmonella*

*choleraesuis* ( $<2.0 \times 10^3$  CFU/carrier on September 26, 2001 and  $1.7 \times 10^3$  CFU/carrier on October 24, 2001) and for *Escherichia coli* O157:H7 ( $<2.0 \times 10^3$  CFU/carrier on September 26, 2001) were below the laboratory's acceptance criterion of  $2.0 \times 10^4$  CFU/carrier.

Note: Protocol amendments/deviations were reviewed and found to be acceptable.

## V RESULTS

The results presented in this section are grouped by product formulation. DynCorp used data submitted in each of the MRIDs to verify the accuracy of all calculated/reported percent reduction values. No inconsistencies were found. Because of the large amount of data contained in the data package, this report does not present control carrier data and test carrier recovery data.

### A. Clorox Trapeze, Formula F2001.0086

MRID Number	Organism	Carrier Type	Percent Reduction	Percent Reduction	Percent Reduction
			Lot No. 7890-85A	Lot No. 7890-129A	Lot No. 7890-129B
456290-07	<i>Staphylococcus aureus</i>	Glass Polyvinyl chloride Glazed ceramic	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9
456290-09	<i>Staphylococcus aureus</i>	Unglazed ceramic	>99.9	>99.9	>99.9
456290-11	<i>Staphylococcus aureus</i>	Glass Polyvinyl chloride Glazed ceramic	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9
456290-07	<i>Enterobacter aerogenes</i>	Glass Polyvinyl chloride Glazed ceramic	>99.9 99.9 99.9	>99.9 >99.9 99.9	>99.9 >99.9 99.9
456290-09	<i>Enterobacter aerogenes</i>	Unglazed ceramic	>99.9	>99.9	>99.9
456290-11	<i>Enterobacter aerogenes</i>	Glass Polyvinyl chloride Glazed ceramic	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9	>99.9 99.9 >99.9

MRID Number	Organism	Carrier Type	Percent Reduction	Percent Reduction	Percent Reduction
			Lot No. 7890-85A	Lot No. 7890-129A	Lot No. 7890-129B
456290-13	<i>Salmonella choleraesuis</i>	Polyvinyl chloride		>99.9	>99.9
456290-14	<i>Salmonella choleraesuis</i>	Glass Polyvinyl chloride Glazed ceramic Unglazed ceramic		>99.9 >99.9 >99.9 >99.9	>99.9 >99.9 >99.9 >99.9
456290-14	<i>Escherichia coli</i> O157:H7	Glass Polyvinyl chloride Glazed ceramic Unglazed ceramic		>99.9 >99.9 >99.9 99.5	>99.9 >99.9 >99.9 >95.0

**B. Clorox Trapeze, Formula F2001.0093**

MRID Number	Organism	Carrier Type	Percent Reduction	Percent Reduction
			Lot No. 7890-130A	Lot No. 7890-130B
456290-08	<i>Staphylococcus aureus</i>	Glass Polyvinyl chloride Glazed ceramic	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9
456290-10	<i>Staphylococcus aureus</i>	Unglazed ceramic	>99.9	>99.9
456290-12	<i>Staphylococcus aureus</i>	Polyvinyl chloride	>99.9	>99.9
456290-08	<i>Enterobacter aerogenes</i>	Glass Polyvinyl chloride Glazed ceramic	>99.9 >99.9 >99.9	>99.9 >99.9 >99.9
456290-10	<i>Enterobacter aerogenes</i>	Unglazed ceramic	>99.9	>99.9

MRID Number	Organism	Carrier Type	Percent Reduction	Percent Reduction
456290-12	<i>Enterobacter aerogenes</i>	Polyvinyl chloride	>99.9	>99.9
456290-16	<i>Salmonella choleraesuis</i> ATCC 10708	Glass	>99.9	>99.9
		Polyvinyl chloride	>99.9	>99.9
		Glazed ceramic	>99.9	>99.9
		Unglazed ceramic	>99.9	>99.9
456290-16	<i>Escherichia coli</i> O157:H7 ATCC 43888	Glass	>99.9	>99.9
		Polyvinyl chloride	>99.9	>99.9
		Glazed ceramic	>99.9	>99.9
		Unglazed ceramic	>99.4	>88.8

## VI CONCLUSIONS

### A. Clorox Trapeze, Formula F2001.0086

The applicant submitted test results from four studies (MRID Nos. 456290-07, -09, -13, and -14) to demonstrate the efficacy of Clorox Trapeze, Formula F2001.0086 as a sanitizer on non-food contact surfaces for a contact time of 30 seconds. From a "pass/fail" perspective, study results appear to support the use of Formula F2001.0086 as a sanitizer against all challenged microorganisms, with the exception of *Escherichia coli* O157:H7. Note that the studies conducted against *Enterobacter aerogenes* and *Staphylococcus aureus* had information deficiencies and were not conducted according to EPA standards. For many studies, the geometric means of the carrier control for a number of microorganisms on various types of surfaces were below the acceptance criterion of  $7.5 \times 10^5$  CFU/carrier indicated in ASTM Method E1153. However, all carrier control data met the acceptance criterion of the laboratory conducting the testing.

In addition, although studies were conducted against all microorganisms on all carrier types using a sprayer to apply the product, only studies for selected microorganisms on selected carrier types were conducted using the assembled floor cleaning tool. This appears to be acceptable, as one would assume that the slight pressure applied during the use of the floor cleaning tool would enhance contact of the test product with the challenged microorganisms. Thus, studies conducted using the sprayer would be more rigorous than studies conducted using the assembled floor cleaning tool.

#### Conclusions for Studies Where Product Was Applied Using a Spray

1. The submitted efficacy data (MRID Nos. 456290-07 and 456290-09) appear to support the use of Clorox Trapeze, Formula F2001.0086 as a sanitizer on non-food contact surfaces when tested against the following microorganisms in the presence of a 5% organic soil load on the following types of surfaces for a contact time of 30 seconds. The product demonstrated at least a 99.9% reduction [i.e., 99.9 or >99.9 percent reduction] in the number of microorganisms within 30 seconds. Although the test data "passed" Agency performance criteria, the applicant failed to report if any of the batches tested were at least 60 days old. Carrier control data met the acceptance criterion of the laboratory conducting the testing; however, this criterion was at variance with the ASTM E1153 criterion.

*Enterobacter aerogenes*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic, Unglazed ceramic

*Staphylococcus aureus*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic, Unglazed ceramic

Discussion of Controls: Neutralization verification testing showed positive growth of the organism in D/E Broth. According to the laboratory, the sterility control results were acceptable. The applicant did not submit the results of the sterility controls. In addition, according to information in MRID 456290-09, the sterility controls for bovine serum demonstrated a colony that was determined to be a contaminant.

2. The submitted efficacy data (MRID 456290-14) appear to support the use of Clorox Trapeze, Formula F2001.0086 as a sanitizer on non-food contact surfaces when tested against the following microorganisms in the presence of a 5% organic soil load on the following types of surfaces for a contact time of 30 seconds. The product demonstrated at least a 99.9% reduction [i.e., ≥99.9 percent reduction] in the number of microorganisms within 30 seconds. Carrier control data met the acceptance criterion of the laboratory conducting the testing; however, this criterion was at variance with the ASTM E1153 criterion.

*Escherichia coli* O157:H7

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic

*Salmonella choleraesuis*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic, Unglazed ceramic

Discussion of Controls: According to the laboratory, all controls met established criteria for a valid test. Results for some controls were provided.

3. The submitted efficacy data (MRID 456290-14) do not support the use of Clorox Trapeze, Formula F2001.0086 as a sanitizer on non-food contact surfaces when tested against *Escherichia coli* O157:H7 in the presence of a 5% organic soil load on unglazed ceramic surfaces for a contact time of 30 seconds. For the two batches of product tested, a 99.5 and a >95.0 percent reduction were reported.

#### Conclusions for Studies Where Product Was Applied Using the Assembled Floor Cleaning Tool

1. The submitted efficacy data (MRID Nos. 456290-11 and 456290-13) appear to support the use of Clorox Trapeze, Formula F2001.0086 as a sanitizer on non-food contact surfaces when

tested against the following microorganisms in the presence of a 5% organic soil load on the following types of surfaces for a contact time of 30 seconds. The product demonstrated at least a 99.9% reduction [i.e.,  $\geq 99.9$  percent reduction] in the number of microorganisms within 30 seconds. Although the test data "passed" Agency performance criteria, the applicant failed to report if any batches tested were at least 60 days old. However, based on information provided in MRID 456290-14, it is likely that at least two lots tested (Lot Nos. 7890-129A and 7890-129B) were at least 60 days old at the time of the experiment. Carrier control data met the acceptance criterion of the laboratory conducting the testing; however, this criterion was at variance with the ASTM E1153 criterion.

*Enterobacter aerogenes*  
*Salmonella choleraesuis*  
*Staphylococcus aureus*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic  
Surface: Polyvinyl chloride  
Surfaces: Glass, Polyvinyl chloride, Glazed ceramic

Discussion of Controls: Neutralization verification testing showed positive growth of the organism in D/E Broth. According to the laboratory, the sterility control results were acceptable. The applicant did not submit the results of the sterility controls.

#### **B. Clorox Trapeze, Formula F2001.0093**

The applicant submitted test results from four studies (MRID Nos. 456290-08, -10, -12, and -16) to demonstrate the efficacy of Clorox Trapeze, Formula F2001.0093 as a sanitizer on non-food contact surfaces for a contact time of 30 seconds. From a "pass/fail" perspective, study results appear to support the use of Formula F2001.0093 as a sanitizer against all challenged microorganisms, with the exception of *Escherichia coli* O157:H7. Note that the studies conducted against *Enterobacter aerogenes* and *Staphylococcus aureus* had information deficiencies and were not conducted according to EPA standards. For many studies, the geometric means of the carrier control for a number of microorganisms on various types of surfaces were below the acceptance criterion of  $7.5 \times 10^5$  CFU/carrier indicated in ASTM Method E1153. However, all carrier control data met the acceptance criterion of the laboratory conducting the testing (i.e., one log lower).

In addition, although studies were conducted against all microorganisms on all carrier types using a sprayer to apply the product, only studies for selected microorganisms on selected carrier types were conducted using the assembled floor cleaning tool. This appears to be acceptable, as one would assume that the slight pressure applied during the use of the floor cleaning tool would enhance contact of the test product with the challenged microorganisms. Thus, studies conducted using the sprayer would be more rigorous than studies conducted using the assembled floor cleaning tool.

#### **Conclusions for Studies Where Product Was Applied Using a Spray**

1. The submitted efficacy data (MRID Nos. 456290-08 and 456290-10) appear to support the use of Clorox Trapeze, Formula F2001.0093 as a sanitizer on non-food contact surfaces when tested against the following microorganisms in the presence of a 5% organic soil load on the following types of surfaces for a contact time of 30 seconds. The product demonstrated at least a

99.9% reduction [i.e.,  $\geq 99.9$  percent reduction] in the number of microorganisms within 30 seconds. Although the test data "passed" the Agency performance criteria, the applicant failed to report if any of the batches tested were at least 60 days old. In addition, only two batches of product were tested. Carrier control data met the acceptance criterion of the laboratory conducting the testing; however, this criterion was at variance with the ASTM E1153 criterion.

*Enterobacter aerogenes*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic, Unglazed ceramic

*Staphylococcus aureus*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic, Unglazed ceramic

Discussion of Controls: Neutralization verification testing showed positive growth of the organism in D/E Broth. According to the laboratory, the sterility control results were acceptable. The applicant did not submit the results of the sterility controls. In addition, according to information in MRID 456290-10, the sterility controls for bovine serum demonstrated a colony that was determined to be a contaminant.

2. The submitted efficacy data (MRID 456290-16) appear to support the use of Clorox Trapeze, Formula F2001.0093 as a sanitizer on non-food contact surfaces when tested against the following microorganisms in the presence of a 5% organic soil load on the following types of surfaces for a contact time of 30 seconds. The product demonstrated at least a 99.9% reduction [i.e.,  $\geq 99.9$  percent reduction] in the number of microorganisms within 30 seconds. Although the test data "passed" Agency performance criteria, only two batches of product were tested. Carrier control data met the acceptance criterion of the laboratory conducting the testing; however, this criterion was at variance with the ASTM E1153 criterion

*Escherichia coli* O157:H7

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic

*Salmonella choleraesuis*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic, Unglazed ceramic

Discussion of Controls: According to the laboratory, all controls met established criteria for a valid test. Results for some controls were provided.

3. The submitted efficacy data (MRID 456290-16) do not support the use of Clorox Trapeze, Formula F2001.0093 as a sanitizer on non-food contact surfaces when tested against *Escherichia coli* O157:H7 in the presence of a 5% organic soil load on unglazed ceramic surfaces for a contact time of 30 seconds. For the two batches of product tested, a  $>99.4$  and a  $>88.8$  percent reduction were reported.

#### Conclusions for Studies Where Product Was Applied Using the Assembled Floor Cleaning Tool

1. The submitted efficacy data (MRID 456290-12) appear to support the use of Clorox Trapeze, Formula F2001.0093 as a sanitizer on non-food contact surfaces when tested against the following microorganisms in the presence of a 5% organic soil load on the following types of surfaces for a contact time of 30 seconds. The product demonstrated at least a 99.9% reduction [i.e.,  $\geq 99.9$  percent reduction] in the number of microorganisms within 30 seconds. Although

the test data "passed" the Agency performance criteria, the applicant failed to report if any of the batches tested were at least 60 days old. However, based on information provided in MRID 456290-16, it is likely that both lots tested were at least 60 days old at the time of the experiment. Carrier control data met the acceptance criterion of the laboratory conducting the testing; however, this criterion was at variance with the ASTM E1153 criterion

*Enterobacter aerogenes*  
*Staphylococcus aureus*

Surfaces: Polyvinyl chloride  
Surfaces: Polyvinyl chloride

Discussion of Controls: Neutralization verification testing showed positive growth of the organism in D/E Broth. According to the laboratory, the sterility control results were acceptable. The applicant did not submit the results of the sterility controls.

## VII RECOMMENDATIONS

### A. Recommendations Regarding Clorox Trapeze, Formula F2001.0086

1. The majority of the proposed label claims regarding Clorox Trapeze, Formula F2001.0086 are not currently acceptable because of deficiencies in the studies. Because no information was provided to verify that any of the batches of test product were at least 60 days old, proposed label claims against the following microorganisms on the following types of non-food contact surfaces for a contact time of 30 seconds are not currently acceptable:

*Enterobacter aerogenes*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic (MRID Nos. 456290-07 and 456290-11)

*Enterobacter aerogenes*  
*Staphylococcus aureus*

Surface: Unglazed ceramic (MRID-456290-09)  
Surfaces: Glass, Polyvinyl chloride, Glazed ceramic (MRID Nos. 456290-07 and 456290-11)

*Staphylococcus aureus*

Surface: Unglazed ceramic (MRID-456290-09)

If the applicant provides information to confirm that studies included studies conducted on product batches that were at least 60 days old, EPA may then want to determine what the appropriate value is for the control carrier performance standard based on a more detailed review of the testing procedures used by the laboratories – an unspecified modification of ASTM E1153. Specifically, EPA would need to determine whether the performance standard used (and achieved) by the laboratory, at variance with ASTM E1153, is acceptable prior to accepting the above label claims for *Enterobacter aerogenes* and *Staphylococcus aureus*.

2. Because the product has not yet met Agency standards to be labeled as a sanitizer for non-food contact surfaces [see previous discussion in Item #1], claims for supplemental organisms cannot be made. Thus, the proposed label claims (as supported by MRID Nos. 456290-13 and 456290-14) are not currently acceptable regarding the use of the product as a sanitizer against *Salmonella choleraesuis* in the presence of a 5% organic soil load on various types of surfaces for a contact time of 30 seconds. If this product is shown to meet Agency standards (to be labeled as a sanitizer for non-food contact surfaces), then the proposed label claims would be acceptable.

3. Efficacy data submitted for *Escherichia coli* O157:H7 (MRID 456290-14) do not support effectiveness of the product at a 30 second contact time in the presence of a 5% organic soil load on unglazed ceramic surfaces. The proposed label did not include claims for this microorganism on unglazed ceramic or other surfaces.

#### **B. Recommendations Regarding Clorox Trapeze, Formula F2001.0093**

1. The majority of the proposed label claims regarding Clorox Trapeze, Formula F2001.0093 are not currently acceptable because of deficiencies in the studies (i.e., two batches of product tested). This product appears to be an alternate formulation of F2001.0086, and the applicant appears to be invoking DIS/TSS-5 standards, as cited in the MRID studies. However, there is no previously registered product for efficacy comparison. Because there is no currently registered product for comparison (which would permit the applicant to submit only minimal confirmatory efficacy data), proposed label claims against the following microorganisms on the following types of surfaces for a contact time of 30 seconds are not currently acceptable:

*Enterobacter aerogenes*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic (MRID 456290-08)

*Enterobacter aerogenes*

Surface: Polyvinyl chloride (MRID 456290-12)

*Enterobacter aerogenes*

Surface: Unglazed ceramic (MRID 456290-10)

*Staphylococcus aureus*

Surfaces: Glass, Polyvinyl chloride, Glazed ceramic (MRID 456290-08)

*Staphylococcus aureus*

Surface: Polyvinyl chloride (MRID 456290-12)

*Staphylococcus aureus*

Surface: Unglazed ceramic (MRID 456290-10)

EPA may choose to register Formula F2001.0086 first (when data gaps have been satisfied), and then accept Formula F2001.0093's data as confirmatory data. As with Formula F2001.0086, EPA may want to determine what the appropriate value is for the control carrier performance standard based on a more detailed review of the testing procedures used by the laboratories – an unspecified modification of ASTM E1153.

2. Because the product has not yet met Agency standards to be labeled as a sanitizer for non-food contact surfaces [see previous discussion in Item #1], claims for supplemental organisms cannot be made. Thus, the proposed label claims (as supported by MRID 456290-16) are not currently acceptable regarding the use of the product as a sanitizer against *Salmonella choleraesuis* in the presence of a 5% organic soil load on various types of surfaces for a contact time of 30 seconds.

3. Efficacy data submitted for *Escherichia coli* O157:H7 (MRID 456290-16) do not support effectiveness of the product at a 30 second contact time in the presence of a 5% organic soil load on unglazed ceramic surfaces. The proposed label did not include claims for this microorganism on unglazed ceramic or other surfaces.

#### **C. General Recommendations**

1. The study methods indicated that "an assembled floor-cleaning tool and wetted applicator pad" was used to expose the test carriers to the product. While this application appears to be similar to the label directions, it does not appear feasible or practical to use a floor-cleaning tool (i.e., ReadyMop Mopping System) to apply product to a 25 x 25 mm (approximately 1 square inch) carrier during testing. EPA may want to request that the applicant provide additional information regarding description of the application of the product during testing.
2. Prior to approving the proposed label, the Agency may want to seek confirmation of the product identity. MRID Nos. 456290-07 through 45629-14 refer to the product as Clorox DOA, whereas, the proposed label identifies the product as Clorox Trapeze. The applicant may have decided to change the product name after testing began.
3. The Agency may also want to request that the applicant add language to the proposed label that states that the product is acceptable for use on "hard non-porous surfaces". Although, the proposed label states the types of floor on which the product can be used (i.e., finished wood, laminate, marble, vinyl, Pergo, Wilsonart, etc.), the term "hard non-porous surfaces" is much clearer.
4. EPA does not currently require a simulated use test for this product type. EPA may wish to recommend that the proposed directions for use as a sanitizer be modified. Because the amount of product to be used is not specified in the proposed label and is totally within the control of the user (and therefore highly variable), the only assurance EPA may have that sufficient product has been applied is if the user truly does ensure that the floor remains wet for 30 seconds after mopping. EPA may want to recommend to the applicant that language, such as that approved for competitor Proctor and Gamble's Cougar product, be modified for use by Clorox Trapeze. This suggested alternate use direction language appears to be supported by the submitted data:

To Sanitize: For use on hard non-porous floors. Use the <Clorox Trapeze> mop to spray floor until thoroughly wet. Let stand for <30 seconds> before mopping, then remove excess liquid. For heavily soiled floors, clean before following sanitizing instructions.

5. Prior to accepting the proposed label, EPA may wish to review the following phrases on the proposed label to determine whether the inappropriate marketing claims are being made. If so, EPA may wish to request that the applicant remove or modify unacceptable claims.

**General Claims, Convenience and Ease of Use (page 3):**

"Effective sanitizing has never been faster or easier"  
"New and improved formula"

**General Claims, Other (page 4):**

"Economy size"  
"Value size"

**Sanitization Claims (page 5):**

*Possible puffery (including comparative statements):*

- "America's home floor sanitizer and/or cleaner"
- "Effective sanitizing has never been faster or easier"
- "Fast acting sanitizer"

*Organisms not specified or statements insufficiently qualified (e.g., by "some" or "many"):*

- "Germ or bacteria fighting formula"
- "Germicide or germicidal"
- "Helps prevent cross-contamination of bacteria or germs on floors within 30 seconds"
- "Kills 99.9% of bacteria or germs on your floors"
- "Kills bacteria while it cleans and sanitizes"
- "Kills germs or bacteria while it cleans"
- "Kills germs or bacteria in 30 seconds"
- "Kills germs or bacteria in kitchens and bathrooms"